IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC, Plaintiffs, v. BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION, Defendants.	Civil Action No. 05-349-GMS Jury Trial Demanded
BAXTER HEALTHCARE CORPORATION, Counterclaimant, v. TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC, Counterdefendants.	**PUBLIC VERSION**

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION *IN LIMINE* NO. 4 TO PROHIBIT ANY EVIDENCE OR ARGUMENT REGARDING ALLEGED COMMERCIAL SUCCESS

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Dated: May 14, 2007
Public Version: May 17, 2007

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Plaintiffs cannot point to any admissible evidence to show that Gamimune N S/D embodies the claim limitations of the patent-in-suit ("the '191 patent"). After all, there is none. Plaintiffs, instead, repeatedly refer to the "sales levels achieved" or the "financial success" of Gamimune N S/D and the claimed "nexus" between those sales and the alleged patented features of Gamimune N S/D. (*See, e.g.*, Opp. at 1, 3.) Yet, as Plaintiffs know, those considerations are completely irrelevant unless they ***first*** establish that the '191 patent is actually embodied by Gamimune N S/D. They cannot. Indeed, Plaintiffs' primary technical expert, Dr. Jeffrey Ravetch, concedes so in his deposition – something Plaintiffs do not contest in their opposition. For these reasons, Baxter's motion to exclude evidence regarding the purported commercial success of Gamimune N S/D should be granted.

Revealingly, at no point in their opposition do Plaintiffs dispute or explain away Dr. Ravetch's fatal deposition testimony that REDACTED [1] (Rogaski Supp. Decl., Ex. 18 at 219:18-23.)[2] Consequently, Dr. Ravetch should be precluded from offering an opinion at trial REDACTED (*id.*), as requested by Baxter's motion.

In their opposition, Plaintiffs list six items that allegedly demonstrate how Gamimune N S/D was manufactured using the claimed '191 invention. (Opp. at 2-3.) All are inapposite.

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[1] Claim 1 is the only independent claim of the '191 patent. To embody the '191 patent, Gamimune N S/D must meet every limitation of claim 1. It does not. Neither Dr. Ravetch nor any of Plaintiffs' other witnesses testified to the contrary.

[2] The critical admission by Dr. Ravetch (among many others) made during his deposition is as follows:

Q. REDACTED

A. REDACTED

(Rogaski Supp. Decl., Ex. 18 at 219:18-23.)

For its first item, Plaintiffs curiously cite, *as evidence*, their own interrogatory response identifying Gamimune N S/D as a product embodying the '191 patent. (Opp. at 2.) As rank hearsay, Plaintiffs' own self serving interrogatory response plainly does not constitute admissible evidence. *See* Fed. R. Evid. 802. Plaintiffs then cite their manufacturing process flow-diagram from the Biologics License Application (BLA) for Gamimune N S/D. (Opp. at 2.) This is another peculiar item to cite because nothing in the process flow diagram refers to anticomplement activity (ACA) – the self-created problem that the '191 patent purportedly addresses – much less an "increased" level of ACA after the solvent/detergent treatment in Gamimune N S/D or a subsequent reduction of ACA to an "acceptable" level.

As their third and fourth items, Plaintiffs cite pronouncements made by the inventor of the '191 patent, Dr. William Alonso, regarding test results that reveal REDACTED (Opp. at 2) However, as Baxter will show at trial, Dr. Alonso misrepresented those results because he knew that ACA did ***not*** REDACTED increase after the solvent/detergent treatment. Moreover, Plaintiffs do not show the relevance of these test results regarding whether Gamimune N S/D embodies the '191 patent.

As their final item, Plaintiffs cite the sales figures of Gamimune N S/D in 1998 and 1999. Yet, all the sales in the world will still be irrelevant for the commercial success inquiry if the product does not embody the patent.

The only thing Plaintiffs can muster to directly connect the '191 patent and Gamimune N S/D is Dr. Ravetch's rebuttal expert report at paragraph 76. (Rogaski Supp. Decl., Ex. 19.) But Dr. Ravetch is loose – purposely so – with his terminology as to whether Gamimune N S/D actually embodies the required claim limitations of the '191 patent. Paragraph 76 states that the REDACTED

(*Id.* (emphasis added).) Being REDACTED"

REDACTED a patent is not the same as actually ***embodying*** the claim limitations of the patent, as required under the commercial success inquiry. On this narrow – but critical – matter, Plaintiffs have REDACTED

More fundamentally, Dr. Ravetch's opinion does not satisfy the mandate of Federal Rule of Procedure 26(a)(2)(B), which requires that an expert report "contain a ***complete*** statement of all opinions to be expressed and the basis and reasons therefor…." Fed. R. Civ. P. 26(a)(2)(B) (emphasis added). Dr. Ravetch's report falls woefully short of this standard. He cites no documents – other than the '191 patent itself – linking the manufacturing process of Gamimune N S/D with the claims of the '191 patent. Moreover, before taking an abrupt break in his deposition, Dr. Ravetch confirmed that he could not identify any specific document – other than every document in his "Documents Considered" list – that would support his commercial success opinion. (Rogaski Supp. Decl., Ex. 18 at 219:15-224:6.)

Plaintiffs have no evidence that Gamimune N S/D embodies the claims of the '191 patent. Their alleged evidence of commercial success, therefore, should be excluded at trial.

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CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on May 17, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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